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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,883	02/12/2004	Alexander V. Chervonsky	JMY-P01-001	6714

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FISH & NEAVE IP GROUP
ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
LYLES, JOHNALYN D	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,883	CHERVONSKY ET AL.	
	Examiner	Art Unit	
	Johnalyn Lyles	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to a method of modulating homing of T cells to the pancreas with an agonist or an antagonist of the chemokine CCL21, classified in class 435, subclass 7.1 or classified in class 436, subclass 501.

II. Claims 11-20, drawn to a method of modulating homing of T cells to the pancreas with an agonist or an antagonist of a chemokine receptor of T cells, classified in class 435, subclass 7.1 or classified in class 436, subclass 501.

III. Claims 21-32, drawn to a method of treating an individual suffering from insulin-dependent diabetes by administering an antagonist of the chemokine CCL21, classified in class 424, subclass 130.1 or classified in class 514, subclass 2.

IV. Claims 33-44, drawn to a method of treating an individual suffering from insulin-dependent diabetes by administering an antagonist of a chemokine receptor of the T cells, classified in class 424, subclass 130.1 or classified in class 514, subclass 2.

V. Claim 45, drawn to a method of modulating homing of T cells to the pancreas in an individual by administering to the individual an agonist or

an antagonist of the chemokine CCL21, classified in class 424, subclass 130.1 or classified in class 514, subclass 2.

VI. Claim 46, drawn to a method of modulating homing of T cells to the pancreas in an individual by administering an agonist or an antagonist of a chemokine receptor, classified in class 424, subclass 130.1 or classified in class 514, subclass 2.

VII. Claim 47, drawn to a method of preventing or reducing the onset of insulin-dependent diabetes in an individual by administering an antagonist of CCL21, classified in class 424, subclass 130.1 or classified in class 514, subclass 2.

VIII. Claim 48, drawn to a method of preventing or reducing the onset of insulin-dependent diabetes in an individual by administering an antagonist of a chemokine receptor of T cells, classified in class 424, subclass 130.1 or classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different methods of Groups I-VIII are not disclosed as capable of use together, have different reagents, and different effects. Groups I-II, and V-VI are methods of modulating homing of T cells to the pancreas with different agonist or

antagonists in an *in vitro* or *in vivo* system. The method of Group I is by contacting cells with an agonist or an antagonist of the chemokine CCL21, Group II is by contacting the cells with an agonist or an antagonist of the chemokine receptor of T cells, and Groups V and VI are by administering the agonist or antagonist of the chemokine CCL21 and the chemokine receptor, respectively to an individual. Groups III-IV and VII-VIII also have different effects, different agonists or antagonists and are *in vivo*. Group III is a method of treating an individual suffering from insulin-dependent diabetes by administering an antagonist of the chemokine CCL21, whereas Group IV is by administering an antagonist of a chemokine receptor of the T cells. Group VII is a method of preventing or reducing the onset of insulin-dependent diabetes in an individual by administering an antagonist of CCL21, whereas Group VIII is by administering an antagonist of a chemokine receptor of T cells.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Further Restriction within Groups

Further election is **required** with the restriction as set forth in the following Groups (A-B). If Applicant elects invention I-IV, Applicant must further elect one (1) chemokine receptor and one (1) agonist or antagonist for the invention as set forth below. **For Applicant to be fully responsive** to the restriction requirement, **(1) chemokine receptor from Group A and (1) agonist or antagonist from Group B**

must be elected for the elected invention. Applicants are advised that this is not a species election.

If Applicant elects Invention I-IV, then select one chemokine receptor from Group A:

A. Chemokine receptor

1. CCR7
2. CXCR3

If Applicant elects Invention I-IV, then also select one agonist or antagonist from Group B:

B. Agonist or Antagonist

1. an antibody (1) against CCL21
2. a mutated form (1) or a mimic (1) of CCL21
3. a peptidomimetic (1)

Although classifications for the receptors or the agonists and antagonists may be overlapping, each represents a patentably distinct product, the receptors having different amino acid sequences, structures and activities; the antibodies having different amino acid sequences and binding specificities; and the mutated form or mimic of CCL21 and the peptidomimetic having different structures and activites. Thus, each would require separate sequence and or technical searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Johnalyn Lyles whose telephone number is 571-272-3433. The examiner can normally be reached on M-F 8 am - 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jdl

SHARON TURNER, PH.D.
PRIMARY EXAMINER
8-1-05